REMARKS

In view of the foregoing amendments and following remarks responsive to the Office Action dated February 19, 2004, Applicant respectfully requests favorable reconsideration of this application.

Applicant respectfully thanks the Office for the indication found in section 6 of the Office Action that claims 4-6 recite allowable subject matter and are objected to merely as being dependent upon a rejected base claim.

Applicant acknowledges with thanks the Office's indication in section 1 of the Office Action that the information disclosure statements submitted on March 5, 2002 and June 2, 2003 have been considered.

Applicant also respectfully acknowledges with thanks the withdrawal of the previous restriction requirements in section 3 of the Office Action. As noted in section 2 of the Office Action, all claims are now being considered.

In section 3 of the Office Action, the Office objected to the abstract as being too long. Applicant herewith submits a shortened abstract.

The Present Invention

The present invention is a method and apparatus for delivering a stent into a body lumen. With reference to Figures 5 and 6, a stent delivery device in accordance with the present invention includes an outer tube 203 completely surrounding an inner tube 201. Slidably engaged on the inner tube 201 between the inner tube and the outer tube 203 is a carriage assembly 211 that includes a foldable sleeve 206 extending distally from the carriage assembly 211. The

carriage also engages the outer tube so that movement of the outer tube can cause the carriage and sleeve to be drawn along with the outer tube causing the carriage to slide on the inner tube under force applied from the outer tube as described more fully below.

The carriage assembly 211 and sleeve 206 are designed to make it easy for a physician to insert a self-expanding stent 205 into the lumen between the inner tube 201 and the outer tube 203. Particularly, the sleeve is carried on the inner tube so that the inner tube can be positioned relative to the outer tube such that the sleeve extends beyond the distal end of the outer tube whereby the sleeve can be unfolded. The distal end 207b of the sleeve 206 is large enough to make it easy for a physician to insert an end of a self-expanding stent into the sleeve. Then, the inner tube can be drawn proximally so as to cause the sleeve to be drawn into the outer tube 203 and become folded between the inner tube and outer tube. Accordingly, the stent, having an end inserted in the sleeve, also is drawn into the outer tube, thereby capturing the stent in a radially-constricted condition within the lumen between the inner tube 201 and the outer tube 203. When the stent is ready for release, the outer tube 203 is drawn proximally relative to the inner tube 201.

Figures 8 and 9 illustrate two alternative designs that permit the outer tube 203 to apply a greater force to the carriage 211 than the frictional force between the carriage and the inner tube 201 so that the carriage 211 will be drawn proximally along with the outer tube 203 when the outer tube is drawn proximally, even though the carriage is frictionally engaged with the inner tube. Since the

carriage 211 is slidable on the inner tube and proximal of the blocking element, it will slide proximally on the inner tube 201 and be drawn proximally with the outer tube 203.

The Prior Art Rejection

In sections 4 and 5 of the Office Action, the Office rejected claims 1-4 and 7-21 under 35 U.S.C. 103(a) as being unpatentable over Fitz (U.S. Patent No. 6,306,163). Particularly, the Office asserted that Fitz discloses an apparatus and method for delivering a self-expanding stent and filter into a body lumen wherein the apparatus includes all the limitations of the claims except for the outer tube. The Office asserted that it is known in the art to include an introducer or an outer tube for advancing an intravascular delivery apparatus into a body lumen in order to prevent the intravascular delivery apparatus from accidentally deploying an implant at an undesired site as well as to prevent an intravascular delivery apparatus from damaging the vessel wall during navigation to a treatment site. The Office concluded that it, therefore, would have been obvious to employ an outer tube in Fitz's apparatus in order to prevent the apparatus from accidentally deploying an implant at an undesired site as well as to prevent an intravascular delivery apparatus from damaging the vessel wall during navigation to the treatment site.

Applicant respectfully traverses. Particularly, the function of the sleeve in the present invention and the function of the sheath in Fitz are inapposite such that, not only would it not be obvious to incorporate an outer tube into Fitz, but

there are several additional elements recited in the claims that also are not found in Fitz.

The Fitz Reference

Fitz discloses an apparatus and method for treating stenosed cerebral blood vessels and, particularly for deploying a self-expanding stent in a body vessel while preventing embolic migration. With reference to Figures 11-14, the system includes a catheter 62 with a self-expanding stent 66 mounted at its distal end and trapped within a restraining sheath 64 that is capable of both expanding and retracting. The restraining sheath 64 is forced open when it is in position and ready for deployment by an umbrella-like expansion structure 40, 42, 44 such as one of the three alternate structures shown in figures 1, 3, and 6 of Fitz. The primary purpose of the sheath 64 and umbrella-like expansion mechanism is to cause the sheath to expand and seal off the body lumen 60 temporarily while the system generates a negative pressure that will break loose embolic material 72 and cause it to flow toward a filter 70 within the delivery apparatus. The sheath 64 prevents the embolic material 72 from getting around the delivery mechanism but instead traps the embolic material 72 between the sheath 64 and the catheter tube 62. The sheath can then be retracted into its radially constricted state, thereby trapping the embolic material between the tube 62 and the sheath 64. The delivery apparatus is then withdrawn, taking the embolic material 72 away with it.

In accordance with the disclosure of Fitz, the proximal end of the sheath as well as the proximal end of the expanding mechanism are fixed to the catheter. See, for instance, column 3, lines 41-43, column 3, lines 58-60, and column 4, lines 3-6.

Accordingly, not only does Fitz fails to disclose an outer tube as claimed, it also fails to disclose that the sheath is slidably engaged with said inner tube as claimed. Furthermore, it fails to disclose "a blocking element fixed to said inner tube near said distal end of said inner tube and adapted to block a stent inserted into said sleeve from becoming situated proximally of said blocking element and to blocks said capturing element from becoming situated distally of the predetermined point relative to said inner tube", as claimed.

In accordance with the principles of present invention, the sleeve slides on the inner tube so that it can be drawn proximally along with the outer tube to release the stent from the delivery catheter.

In Fitz, on the other hand, the stent is released from the sheath because the sheath expands radially and retracts proximally simultaneously by means of the operation of the expansion mechanism. Column 4, lines 38-43. The present invention is superior to Fitz because it has no expansion mechanism to expand the sleeve. The expansion force is provided by the self-expanding stent itself. All that is needed to release the stent is to draw the outer tube proximally. Since the sleeve slides on the inner tube, it is drawn along with the outer tube when it is retracted, thus releasing the stent. This is a very different release technique that disclosed in Fitz.

MPEP §2143 lists three requirements for a proper rejection based on obviousness, namely:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The present invention clearly is non-obvious over Fitz at least because Fitz does not teach or suggest all of the claim limitations. The presently pending claims clearly recite significant, patentably-distinguishing limitations, such as the aforementioned slidable engagement of the sleeve on the inner tube, the blocking element, and the outer tube. In Fitz, there is no blocking element because the sheath is fixedly attached to the inner tube, eliminating any purpose of such a blocking element. Furthermore, in Fitz, the sheath is fixedly attached to the inner tube, it is not slidably engaged with the inner tube. See, for instance, column 3, lines 41-43, column 3, lines 58-60, and column 4, lines 3-6.

Referring specifically to the claim language, there are so many limitations of independent claim 1 that are not found in Fitz that Applicant has reproduced below a copy of the entire claim with underlining indicating the portions of the claim that are not met by Fitz.

> 1. An apparatus for delivering a self expanding stent into a body lumen comprising:
> an outer tube having a proximal end and a distal end and sized to hold a self-expanding stent therein in a radially constricted condition;
> an inner tube within said outer tube having a proximal end and a distal end;

a capturing element comprising a foldable sleeve slidably engaged with said inner tube, said sleeve having a proximal end and a distal end, said proximal end being smaller than said outer tube and said distal end being larger than said outer tube, said capturing element carried on said inner tube such that said distal end of said sleeve can extend beyond said distal end of said outer tube in an unfolded condition and said sleeve can be drawn into and become folded within said outer tube when said inner tube is drawn proximally relative to said outer tube, whereby a stent having an end inserted into said distal end of said sleeve is drawn into said outer tube, thereby becoming captured in a radially constricted condition within said outer tube; and

a blocking element fixed to said inner tube near said distal end of said inner tube and adapted to block a stent inserted into said sleeve from becoming situated proximally of said blocking element and to block said capturing element from becoming situated distally of a predetermined point relative to said inner tube.

Claims 2-14 depend from claim 1 and, therefore, distinguish over Fitz for at least all of the reasons set forth above in connection with claim 1. In addition, many of the dependent claims recite even further distinguishing features. For instance, claim 2 recites that the blocking element is a band fixed to the inner tube. As noted above, Fitz does not disclose a blocking element at all.

Claim 3 recites that the capturing element comprises a "carriage at least substantially circumscribing said inner tube so as to be slidable longitudinally on said inner tube". As noted above, Fitz's sheath is fixedly attached to the inner tube, not slidably attached.

Claim 9 recites that the distal end of the inner tube extends beyond the blocking element, whereby a stent inserted into said sleeve is captured between said inner tube and said outer tube. Fitz does not have a blocking element.

Claim 10 recites that "said inner tube does not extended distally of said the capturing element". It is quite clear from the figures of Fitz that catheter 12 extends beyond the sheath.

Claim 12 recites that the stent is a stent-graft. This is not disclosed in Fitz.

Claim 13 recites that the stent is a covered stent. This is not disclosed in Fitz.

Claim 14 recites that the capturing element "includes apertures for allowing fluids introduced between said outer tube and said inner tube to flow between said proximal end of said outer tube and said distal end of said outer tube". This is the exactly opposite to the purpose of Fitz. First, Fitz, of course, does not disclose an outer tube. However, even more fundamentally, the whole purpose of Fitz is to prevent the flow of fluids past the sheath. Thus, any assertion that it would be obvious to include an outer tube in Fitz and permit fluid to flow between the inner tube and outer tube would be directly contrary to the teachings on Fitz.

Turning to independent claim 15, it recites a method of loading a stent into a stent delivery apparatus. Fitz contains no relevant teaching with respect to claim 15. Applicant has reviewed Fitz in its entirety and it Fitz contains no disclosure as to how the stent is loaded into the delivery apparatus. Therefore, Fitz disclose none of the limitations of claim 15. Particularly, claim 15 recites the steps of "positioning said inner tube such that said distal end of said capturing element extends beyond said distal end of said outer tube". Fitz does not disclose an outer tube. Accordingly, it cannot possibly disclose this step.

Claim 15 also recites "inserting an end of a stent into said distal end of said sleeve". As noted above, Fitz contains no disclosure whatsoever as to how the stent is placed in the sheath.

Finally, claim 15 recites the step of "drawing said inner tube proximally relative to said outer tube so as to draw said sleeve and said stent into said outer tube, thereby capturing said sleeve and said stent in said outer tube in a radially constricted condition". Once again, Fitz cannot possibly teach this step as there is no outer tube or any disclosure of how the stent gets within the sleeve.

Dependent claims 16-21 distinguish over Fitz for all of the reasons discussed above in connection with claim 15, from which they each dependent directly or indirectly. In addition, the dependent claims add further distinguishing features over Fitz. For instance, claim 16 describes a method for deploying the stent from the stent delivery apparatus which recites the step of "drawing said outer tube proximally relative to said inner tube and said stent so as to release said stent from its radially constricted condition". Fitz does not teach this limitation as it does not have an outer tube that can be drawn proximally.

Claim 17 depends from claim 15 and adds that step 2 comprises "inserting said stent into said sleeve until an end of said stent abuts said blocking element". Since Fitz does not disclose the blocking element, it cannot possibly disclose this recitation.

Claim to 18 depends from claim 17 and adds that the blocking element "blocks said stent from being drawn along with said outer tube". As Fitz does not

disclose either an outer tube or a blocking element, it cannot possibly meet the limitations of this claim.

Claim 19 depends from claim 18 and adds that the blocking element "comprises a band fixedly attached to said inner tube distally of said proximal end of said sleeve and wherein, in step (5), said sleeve is drawn along with said outer tube." Fitz cannot possibly disclose these recitations since it does not have an outer tube, a blocking element, or a sleeve that can be drawn along with said outer tube (since Fitz's sheath is a fixed to the inner tube).

Claim 20 adds that the capturing element comprises "a carriage to which the proximal end of said sleeve is fixedly attached, said carriage circumscribing and frictionally engaging said inner tube so as to be slidable relative to said inner tube upon application of force and wherein an outer surface of said carriage is adapted to engage said outer tube such that said capturing element does not moved distally relative to said outer tube when said inner tube is moved distally relative to said outer tube, and wherein, in step (5), said sleeve is drawn along with said outer tube due to said engagement with said outer tube". Fitz fails to disclose virtually every recitation in claim 20 as it does not disclose (1) a blocking element, (2) an outer tube, (3) that the sleeve is slidable on the inner tube, (4) that the carriage is adapted to engage the outer tube so that the capturing element does not move relative to the outer tube yet slides on the inner tube when the inner tube is moved distally, or (5) engagement of the sleeve with the outer tube.

In view of the foregoing, applicant respectfully requests that the Office allow all pending claims at this time.

Applicant has herein amended claims 19 and 20 to correct obvious clerical errors. For instance, in claim 20, the word "to" was missing after the word "due". Further, in claim 19, the recitation "said capturing element is slidably engaged to said inner tube" has been deleted since that limitation was already found in a claim from which claims 19 depends.

Respectfully submitted,

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